UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

EMILY SHERWOOD Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; & MERCK & CO., INC. Defendants.	CIVIL ACTION NO: 2:10-cv-00200-GZS FIRST AMENDED COMPLAINT & DEMAND FOR JURY TRIAL

Plaintiff Emily Sherwood, by and through her attorneys of record, hereby files this Complaint & Demand for Jury Trial against Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Corporation (hereafter collectively as "Bayer"), as well as, Merck & Co., Inc. ("Merck") (all three defendants collectively as "Defendants"), and states on information and belief as follows:

INTRODUCTION

1. This case involves the fluoroquinolone antibiotic, moxifloxacin.

2. Moxifloxacin was designed, formulated, tested, promoted, marketed, sold and/or distributed by Defendants in the United States under the brand name Avelox® from 1999 through the present.

3. Avelox® was approved by the United States Food and Drug Administration ("FDA") for the treatment of a number of serious bacterial infections. However, Defendants market Avelox® as a first line therapy for common bronchitis and sinusitis infections for which many safer alternative antibiotics are available.

4. Upon information and belief, as compared to other fluoroquinolone antibiotic drugs currently available on the U.S. market, Avelox® causes a higher incidence of liver injury, including hepatitis and fulminant liver failure, none of which was adequately disclosed to Plaintiff and her healthcare provider(s) at the time Plaintiff was prescribed and ingested Avelox®.

5. This Complaint asserts claims against Defendants for strict product liability for design defect; strict product liability for failure to warn; negligence; breach of express and implied warranties for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of Avelox®; fraud; unjust enrichment; and violations of Maine's Unfair Trade Practice statute.

JURISDICTION

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the prescription drug Avelox® within this judicial district and because Defendants are subject to personal jurisdiction within the State of Maine.

PARTIES

8. Plaintiff Emily Sherwood is a citizen and resident of Saco, Maine.

9. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Pine Brook, New Jersey and/or Wayne, New Jersey. At all

times relevant herein, Defendant Bayer HealthCare Pharmaceuticals, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the prescription antibiotic Avelox® in interstate commerce and throughout the State of Maine.

10. Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pittsburgh, Pennsylvania. Bayer Corporation is the North American subsidiary of Bayer AG. Bayer Corporation provides the corporate-center functions that support Bayer subgroups in North America, including Defendant Bayer HealthCare Pharmaceuticals, Inc. At all times relevant herein, Defendant Bayer Corporation tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the prescription antibiotic Avelox® in interstate commerce and throughout the State of Maine.

11. Defendant Merck & Co., Inc. is a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey. On November 4, 2009, Merck & Co., Inc. merged with Schering-Plough Corporation in a "reverse merger" whereby Merck & Co., Inc. became a subsidiary of Schering-Plough Corporation and Schering-Plough Corporation renamed itself Merck & Co., Inc. continuing as the surviving public corporation. At all times relevant herein, Defendant Merck & Co., Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the prescription antibiotic Avelox® in interstate commerce and throughout the State of Maine.

MISNOMER/ALTER-EGO

12. In the event any parties are misnamed or not included herein, it is Plaintiff's contention that such a misnomer and/or such parties are/were "alter egos" of parties named herein. Alternatively, Plaintiff contends that such "corporate veils" should be pierced to hold such parties properly included in the interest of justice.

GENERAL FACTUAL ALLEGATIONS

13. Moxifloxacin is a broad spectrum synthetic antibacterial agent manufactured by Bayer and marketed and sold in the United States in oral tablet, IV solution, and ophthalmic solution under the brand name Avelox® by Bayer and Bayer's marketing partner, Defendant Merck & Co., Inc.

14. Avelox® functions by inhibiting bacterial topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination.

15. Avelox® is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

16. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

17. Twenty years later, in the early 1980s, fluorinated derivates of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

18. Fluoroquinolones have long been associated with serious side effects, including liver toxicity. Indeed, many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

19. Bayer submitted a New Drug Application ("NDA") for Avelox® on December 9, 1998.

20. With the patent for Cipro® (Bayer's other blockbuster fluoroquinolone) set to expire in 2003, Defendants set out to develop and effectively market Avelox® in order to be more competitive with 3rd and 4th generation fluoroquinolones, including Levaquin®. Avelox® quickly became Bayer's heir apparent and successor to Cipro®.

21. Concerns regarding the hepatotoxicity of Avelox® began to surface within clinical trials submitted as a part of the Avelox® NDA. For example:

- In Study No. 0124 – a clinical study conducted to support the indication for Acute Bacterial Exacerbation of Chronic Bronchitis – numerous participants suffered elevated liver enzymes while on Avelox® therapy.
- In Study No. 0140 – a prospective, randomized, double blind clinical study conducted to support an indication for Community Acquired Pneumonia

comparing the safety and efficacy of moxifloxacin to amoxicillin – the FDA Medical Officer Reviewer commented on the disparity in the incidence of liver injury between Avelox® and the comparator drug: "an additional noteworthy finding was the incidence of drug-related cholestatic jaundice, which was noted in 1.5% (3/200) patients treated with moxifloxacin and in 0.5% (1/208) patients treated with amoxicillin."

- In Study No. 0119 – a multinational, multicentre, prospective, randomized, double blind clinical study to compare the efficacy and safety of moxifloxacin and clarithromycin in patients with Community Acquire Pneumonia – the second most common drug related adverse event reported in patients receiving 400 mg of moxifloxacin was liver function test abnormalities (7.1%).
- In Study D96-025 – a prospective, uncontrolled, non-blind clinical study of the safety of moxifloxacin 400 mg once daily for 10 days for the treatment of Community Acquired Pneumonia – 11% of the moxifloxacin exposed study participants experienced elevated liver enzymes (SGPT/ALT).

22. On December 9, 1999, over objections of FDA Medical Review Officers and members of the Anti-Infective Drugs Advisory Committee, the FDA approved Avelox® for marketing despite the fact that clinical studies submitted within the NDA failed to show any advantage of Avelox® over comparator drugs studied.

23. The FDA's initial approval for Avelox® in December 1999 included three treatment indications: Acute Bacterial Exacerbation of Chronic Bronchitis, Acute Bacterial Sinusitis, and Community Acquired Pneumonia.

24. The FDA later approved four additional treatment indications for Avelox® for the adult population: Uncomplicated Skin and Skin Structure Infections (April 2001), Community Acquired Pneumonia caused by multi-drug resistant Streptococcus pneumonia (May 2004), Complicated Skin and Skin Structure Infections (June 2005), and Complicated Intra-Abdominal Infections (November 2005).

25. Although the initial prescribing information for Avelox® mentioned "jaundice" and "hepatic necrosis" as possible hypersensitivity reactions within the Warnings section and "abnormal liver function test (1%)" and "cholestatic jaundice" within the Adverse Reactions section of the label, these complications were buried in a long list of potential side effects; they were not highlighted in any way, such as with bolded lettering or a separate heading such as "Hepatotoxicity." As importantly, hepatitis was not included as an adverse reaction anywhere in the label.

26. On December 13, 1999, Bayer issued a press release stating that "Avelox™ does not cause . . . serious liver toxicity in patients, unlike many other antibiotics."

27. Not surprisingly, two days later on December 15, 1999, the FDA wrote Bayer warning the company that its promotion of Avelox® was in violation of the Federal Food, Drug, and Cosmetic Act. In addition to determining that Bayer was promoting Avelox® for unapproved treatment indications, the FDA found that Bayer's claim that Avelox® did not cause serious liver toxicity was an "unsubstantiated superior safety claim" and inconsistent with the drug's label. The FDA mandated that Bayer cease from disseminating false and misleading messages in its promotion of Avelox®.

28. Later, in February 2003, Bayer modified the Avelox® prescribing information to include "hepatitis (predominantly cholestatic)" as a potential side effect within the Post-

Marketing Adverse Event Reports subsection of the Adverse Reactions section of the label. No update regarding "hepatitis (predominantly cholestatic)" was made to either the Warnings or Precautions sections of the label. Again, "hepatits (predominantly cholestatic)" was buried in a long list of side effects; it was not highlighted in any way, such as with bolded lettering or a separate heading. Furthermore, the Post-Marketing Adverse Event Reports subsection equivocally noted that "[b]ecause these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure."

29. By no later than July 2005, Avelox® was included on the Medicines and Healthcare products Regulatory Agency's (the British equivalent of the FDA) ("MHRA") "Black Triangle List" for prescription medications requiring intense surveillance.

30. On May 31, 2007, Bayer "revamped" the Hypersensitivity subsection of the Warnings section of the Avelox® label in the United States. In addition to making changes to the layout of the Hypersensitivity subsection, Bayer removed "eosinaphilia" from the list of clinical manifestations of hypersensitivity reactions and added in approximately twenty-one new clinical manifestations "some due to hypersensitivity and some due to uncertain etiology" ranging from arthralgia to pancytopenia. Lumped in with these new potential hypersensitivity reactions were "hepatitis" and "acute . . . [hepatic] failure". The phrase "hepatic failure, including fatal cases" was also added to the Adverse Reactions section of the Avelox® label. No "Dear Healthcare Professional" letter was sent to physicians in the United States regarding this label change. The label change also did not become available in the Physician's Desk Reference – a commercially published and widely used compilation of manufacturers' prescribing

information on prescription drugs – until 2009 after Mrs. Sherwood had been prescribed and consumed Avelox®.

31. In November 2007, the MHRA announced that changes had been implemented to the prescribing information for Avelox® in Europe warning of the risk of potentially fatal liver failure and reminding physicians to be vigilant of the early signs and symptoms of liver injury.

32. In February 2008, Bayer Schering Pharma issued a "Dear Healthcare Professional" letter in Europe warning physicians that Avelox® "is associated with a risk of developing fulminant hepatitis potentially leading to life threatening liver failure." The letter further highlighted for physicians:

> The liver injuries possibly related to moxifloxacin were more commonly of cholestatic or mixed hepatocellular-cholestatic than of hepatocellular type. Onset of symptoms was usually between 3 and 10 days. Isolated cases of delayed hepatotoxic effects were also identified and usually occurred 5 to 30 days after cessation of moxifloxacin therapy. . . . As a consequence of this review, Bayer has revised the product information for moxifloxacin across the EU.

No similar "Dear Healthcare Professional" letter has ever been sent to doctors in the United States.

33. In June 2008, following a safety review of moxifloxacin-containing medications carried out by German health authorities, including eight cases of fatal liver injury, the MHRA grew increasingly concerned about the use of Avelox® for the treatment of Acute Bacterial Sinusitis, Acute Exacerbations of Chronic Bronchitis, and Community Acquired Pneumonia and requested that the European Medicines Agency ("EMEA") issue an opinion on whether these treatment indications for Avelox® should be maintained, changed, or removed from the European market.

34. In July 2008, the EMEA finished its review of the safety information on Avelox® and concluded that the use of moxifloxacin-containing medications for the treatment of Acute Bacterial Sinusitis, Acute Exacerbations of Chronic Bronchitis, and Community Acquired Pneumonia should be restricted due to the safety concerns regarding the increased risk of liver injury and only used when other antibiotics have failed or cannot be used. Additionally, the EMEA required European manufacturers of moxifloxacin-containing medications, including Bayer AG, to strengthen the prescribing information for Avelox® to indicate that "[c]ases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported with moxifloxacin."

35. By January 2009, the Avelox® prescribing information in the United States which had not been updated with respect to hepatotoxicity since May 2007 stood in marked contrast to the prescribing information in Europe. Unlike the U.S. label, the European prescribing information for Avelox® had a section titled "Special warnings and precautions for use" that included the direct statement:

> Cases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported with moxifloxacin (see section 4.8). Patients should be advised to contact their prior to continuing treatment if signs and symptoms of fulminant hepatic disease develop such as rapidly developing asthenia associated with jaundice, dark urine, bleeding tendency, or hepatic encephalopathy. Liver function tests/investigation should be performed in cases where indications of liver dysfunction occur.

36. By no later than September 2009, Bayer included a statement in the prescribing information for Avelox® in Canada identical to the European label that "[c]ases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported with moxifloxacin". More significantly, the Canadian warning appeared in a "Black Box" to

highlight the severity of the risk and was preceded by the heading "Serious Warnings and Precautions." A similar label change has not occurred to date in the U.S.

37. On March 22, 2010, Health Canada issued a notice to Canadian health care professionals and the Canadian public regarding the recent changes to the labeling information for Avelox® in Canada regarding the risk of severe liver injury taking place during moxifloxacin therapy.

38. Similar to Cipro®, Avelox® has proven to be a blockbuster drug for Bayer. In 2007 alone, Avelox® generated international sales of $697.3 million dollars.

SPECIFIC FACTUAL ALLEGATIONS

39. Plaintiff Emily Sherwood was forty-eight years old when she was prescribed and consumed Avelox® for suspected pneumonia in January 2009. On her seventh day of a ten day course of Avelox®, Plaintiff Sherwood experienced jaundice with lower back pain. The following day, she suffered fulminant liver failure which her treating physicians attributed to Avelox®. As a result of her use of Avelox®, Plaintiff Sherwood has suffered severe, permanent and debilitating damages, including but not limited to, two liver transplantations and kidney transplantation. As a further direct and proximate result of using Avelox®, Plaintiff Sherwood has sustained and will sustain future damages, including but not limited to, cost of medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain and suffering.

FIRST CAUSE OF ACTION
STRICT LIABILITY

40. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

41. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and/or sale of Avelox®. Defendants designed, manufactured, marketed, and/or sold Avelox® to medical professionals and their patients, knowing it would be ingested for the treatment of suspected or confirmed bacterial infections.

42. Avelox® as designed, manufactured, marketed and/or sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

43. Avelox® was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Avelox® was in a condition not suitable for its proper and intended use.

44. Avelox® was used by Plaintiff in the manner for which it was intended, that is, for treatment of a suspected bacterial infection. This use resulted in injury to Plaintiff.

45. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of Avelox®. Further, in no way could Plaintiff have known that Defendants had designed, developed, and/or manufactured Avelox® in such a way as to increase the risk of harm or injury to the users of Avelox®.

46. Avelox® is defective in design because of its propensity to cause serious liver injury, including hepatitis and fulminant liver failure.

47. Defendants had a duty to warn the Plaintiff and her treating physician(s) about the defective and dangerous nature of Avelox®.

48. Defendants failed to provide adequate warnings to the Plaintiff and her prescribing healthcare provider(s) about the defective and dangerous nature of Avelox®, including the risk of serious liver injury.

49. Avelox® is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia*, the propensity of Avelox® to cause serious liver injury, including hepatitis and fulminant liver failure; the post-marketing experience with Avelox®; and the numbers of liver-related adverse events reported regarding Avelox®.

50. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Avelox® to Plaintiff.

51. Defendants had knowledge and information confirming the defective and dangerous nature of Avelox®. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and her physicians that Avelox® causes serious liver injury, including hepatitis and fulminant liver failure,

52. As a direct and proximate result of Defendants' unreasonable and wrongful conduct, including the defective and dangerous nature and design of Avelox® and the inadequate warnings, Plaintiff ingested Avelox® and has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of past and future medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
NEGLIGENCE

53. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

54. At all relevant times, Defendants had a duty to exercise reasonable care in the design, testing, manufacture, marketing, sale, and/or distribution of Avelox®, including a duty to ensure that Avelox® did not pose a significantly increased risk of bodily injury to its users.

55. Defendants had a duty to exercise reasonable care in the advertising and sale of Avelox®, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Avelox® that were known or should have been known to Defendants at the time of the sale of Avelox® to the Plaintiff.

56. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and/or distribution of Avelox® because Defendants knew or should have known that Avelox® had a propensity to cause serious liver injury, including hepatitis and fulminant liver failure.

57. Defendants failed to exercise reasonable care in the labeling of Avelox® and failed to issue adequate pre-marketing and/or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious liver injury, including hepatitis and fulminant liver failure.

58. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

59. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

60. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise reasonable care in the design, formulation, manufacture, sale, and/or distribution of Avelox®, Plaintiff ingested Avelox® and has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of past and future medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

61. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

62. Defendants designed, manufactured, marketed, and/or sold Avelox® as has previously been alleged and described herein.

63. At the time Defendants marketed, sold and/or distributed Avelox®, Defendants knew of the use for which Avelox® was intended and impliedly warranted that Avelox® was merchantable, safe and fit for its intended purpose: namely that Plaintiff could ingest Avelox® without the risk of serious injury.

64. Plaintiff, a foreseeable user of Avelox®, and Plaintiff's physician(s), reasonably relied upon Defendants' judgment and implied warranties in prescribing, purchasing and/or consuming Avelox® as intended.

65. Avelox® was defective, unmerchantable, and unfit for ordinary use when sold, and subjected Plaintiff to severe and permanent injuries.

66. Defendants breached their implied warranties because Avelox® was and continues to be neither of merchantable quality nor safe for its intended use in that Avelox® has the propensity to cause serious liver injury, including hepatitis and fulminant liver failure.

67. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness for its intended purpose, Plaintiff ingested Avelox® and has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of past and future medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

68. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

69. Defendants through their marketing program, promotional activities, product labeling, package inserts, and/or other written and verbal assurances expressly warranted to physicians and consumers, including Plaintiff and/or her physician(s), that Avelox® had been shown by scientific study to be safe for its intended use.

70. Plaintiff and/or her physicians reasonably relied upon Defendants' express warranties in purchasing, consuming, and/or prescribing Avelox®.

71. Defendants breached their express warranties because Avelox® as manufactured and sold by Defendants does not conform to these express representations in that Avelox® has a propensity to cause serious liver injury, including hepatitis and fulminant liver failure.

72. As a direct and proximate result of Defendants' breach of its express warranties, Plaintiff ingested Avelox® and has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of past and future medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
FRAUD

73. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

74. Defendants were under a duty and failed to discharge their duty to exercise reasonable care to disclose to Plaintiff and her doctor(s) the defective nature and risks that Avelox® can cause severe and permanent liver injury, including hepatitis and fulminant liver failure, of which they had special knowledge not available to Plaintiff or her doctor(s), and as to which they made affirmative representations in violation of all applicable laws, and actively concealed material facts relating to the defective nature and risks of Avelox®, which were peculiarly within their knowledge, knowing that Plaintiff and her doctor(s) would rely on the presumption that no such facts exist.

75. Defendants knew that Avelox® can cause severe and permanent liver injury, including hepatitis and fulminant liver failure; indeed, Defendants knew that liver injuries associated with Avelox® had occurred for years. Defendants had actual knowledge at the time of sale of Avelox® to the Plaintiff that Avelox® created a risk of serious bodily injury to its users, including hepatitis and fulminant liver failure, based, in part, upon test results, studies,

adverse reaction reports, regulatory action in foreign countries, published reports, and their own clinical trials and post-marketing surveillance of Avelox®.

76. At all times during the course of dealing between Defendants and Plaintiff, Defendants knowingly and recklessly omitted and concealed information peculiarly within their knowledge to the Plaintiff, her doctor(s), the scientific community and to the general public—e.g., the dangers of Avelox®, including the serious risk of liver injury – knowing that the scientific community, the general public, the Plaintiff and her doctor(s), would rely on the presumption that the dangers did not exist.

77. Defendants actively concealed from the Plaintiff, her doctor(s), the scientific community and the general public:

i. that their own test results, clinical trials and/or published studies showed a statistically high risk of serious liver injury. including hepatitis and fulminant liver failure, associated with Avelox®; and/or

ii. that Avelox® was not adequately tested for serious liver injury before or after its introduction on the market; and/or

iii. that Avelox® was, in fact, unsafe as it posed a risk of injury which outweighed any purported benefits.

78. Defendants misrepresented that Avelox® was safe and effective for its intended uses by affirmative misrepresentation, and/or active concealment and omission of material facts regarding the safety and effectiveness of Avelox®, and by their course of conscious or intentional conduct succeeded in selling and marketing a dangerous, defective, and ineffective antibiotic to be ingested by Plaintiff. Defendants intentionally omitted, concealed and/or

suppressed this information from consumers, including Plaintiff and her doctor(s), in order to avoid losses in sales to consumers and market share to their major competitors.

79. Moreover, Defendants engaged in an aggressive marketing strategy, which included false representations regarding the safety profile and known adverse side effects of Avelox® to create the impression and to convey to Plaintiff and the general public that:

i. Avelox® had a favorable safety profile and was fit for human consumption;

ii. the benefits of taking Avelox® outweighed any associated risks; and

iii. the use of Avelox® was safe and had fewer adverse health and side effects than were known or should have been known by Defendants at the time of these representations.

80. The omissions, misrepresentations and concealment described in the preceding paragraphs occurred, without limitation, in the Avelox® warning labels, advertisements and promotional materials, in the Defendants' funded or created scientific reports, and the failure to provide other special notification of the dangers of Avelox® to the Plaintiff or her doctor(s), for example by "Dear Healthcare Professional" letters. The Defendants' statements omitted, concealed, and misrepresented the dangers of serious liver injury, including hepatitis and fulminant liver failure, to Plaintiff and her prescribing doctor.

81. Defendants engaged in fraud by deliberately and affirmatively concealing and failing to disclose adverse reactions of Avelox® to Plaintiff, her doctor(s), the scientific community, and the general public, and by disseminating only positive and misleading scientific data, and by concealing scientific data that showed increased risk of liver-related injury to Plaintiff, her doctor(s), the scientific community, and the general public.

82. The Plaintiff and her doctor(s) relied on the warning labels as they appeared in the prescribing information available to them at the time they consumed and prescribed Avelox®. The applicable warnings concealed and omitted material facts relating to the defective nature and risks of Avelox®. These dangers were peculiarly within the Defendants' knowledge, and were omitted and concealed knowing that Plaintiff and her doctor(s) would rely on the presumption that no such facts exist.

83. Defendants knew or should have known that their representations and omissions regarding the safety of Avelox® were, in fact, false and/or misleading, and actively made such representations and omissions with the intent, design, and purpose that Plaintiff and others, including prescribing physicians, rely on these representations leading to the prescription, purchase and/or consumption of Avelox®.

84. At all times herein, Plaintiff and her doctor(s) were unaware of the dangers of Avelox® with respect to liver injury, including hepatitis and fulminant liver failure, and were reasonably misled by the Defendants' omission of information about this danger.

85. At all times herein, Plaintiff and her doctor(s) were unaware of the falsity underlying Defendants' statements and reasonably believed Defendants' false statements about the safety and efficacy of Avelox® to be true.

86. Plaintiff and her doctor(s) could not have discovered Defendants' fraudulent and misleading conduct at an earlier date through the exercise of reasonable diligence because Defendants actively concealed their deceptive, misleading and unlawful activities.

87. Plaintiff and her doctor(s) did, and could be expected to, reasonably and justifiably rely on Defendants' representations and omissions because Defendants held

themselves out as having expertise and specialized knowledge in the pharmaceutical industry especially in fluoroquinolone development.

88. Plaintiff justifiably relied upon to her detriment and/or was induced by Defendants' false statements and active concealment over the safety of Avelox®, in part, because at no time did Plaintiff or her doctor(s) have the knowledge or expertise necessary to independently evaluate the safety of Avelox®.

89. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately, and/or recklessly, in order to induce Plaintiff to purchase Avelox® and Plaintiff and her doctor(s) did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendants about Avelox® when agreeing to purchase and/or ingest Avelox®.

90. As a direct and proximate result of Defendants' false representations and/or active concealment of material facts regarding the safety and efficacy of Avelox®, Plaintiff ingested Avelox® and has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of past and future medical care, rehabilitation, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT

91. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

92. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and use of Avelox® by Plaintiff.

93. Defendants appreciated and knew of the benefits conferred by the Plaintiff's purchase of Avelox®.

94. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature, and/or fitness that had been represented by Defendants, or that Plaintiff, as reasonable consumers, expected to receive.

95. The acceptance or retention by Defendants of the benefits under such circumstances as to make it inequitable for the Defendants to retain the benefit without payment of its value.

96. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

SEVENTH CAUSE OF ACTION
VIOLATION OF MAINE'S UNFAIR TRADE PRACTICES ACT
(5 M.R.S.A. §§ 205-A – 214)

97. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

98. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and/or sale of Avelox®.

99. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Avelox®, and would not have incurred related medical costs.

100. Specifically, Plaintiff and her prescribing healthcare provider(s) were misled by the deceptive conduct described above.

101. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of 5 M.R.S.A. §§ 205-A – 214.

102. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for Avelox® that she would not have paid had Defendants not engaged in unfair and deceptive conduct.

103. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices in violation of 5 M.R.S.A. §§ 205-A – 214.

104. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell Avelox®. Each aspect of Defendants' conduct combined to artificially create sales of Avelox®.

105. The medical community relied upon Defendants' misrepresentations and omissions in determining which antibiotic to utilize.

106. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

107. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for Avelox®. As a direct and proximate result of Defendants' violations 5 M.R.S.A. §§ 205-A – 214, Plaintiff has sustained economic losses and other damages for which she is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages according to proof, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

2. Special damages according to proof, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, permanent liver impairment, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Punitive damages as allowed by law and in an amount to be determined at trial;

5. Disgorgement of profits;

6. A full refund for all prescriptions paid;

7. Attorneys' fees, expenses, and costs of this action;

8. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

9. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: June 15, 2010

Respectfully submitted,
LEWIS SAUL & ASSOCIATES, P.C.

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